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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,223	12/05/2001	Xiaorong He	C-3409/1/US	4333

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GLOBAL PATENT DEPARTMENT  
POST OFFICE BOX 1027  
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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/008,223	<b>Applicant(s)</b> HE, XIAORONG	
	<b>Examiner</b> Yong S. Chong	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18,20,21,23-37 and 39-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 20-21, 23-37, 39-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/8/2006 has been entered.

Claim(s) 22 has been cancelled. Claim(s) 18, 20-21, 23-37, 39-53 are pending. Claim(s) 18 and 35 have been amended. Claim(s) 18, 20-21, 23-37, 39-53 are examined herein.

Applicant's arguments have been fully considered and found not persuasive for reasons of record. The 103(a) rejection of the last Office Action is maintained and rewritten below to reflect the new amendments to the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18, 20-21, 23-37, 39-53 are rejected under 35 U.S.C. 103(a) as being obvious over Bolt et al. (EP 396,335) in view of Harrison et al. (US Patent 6,086,909).

The instant claims are directed to a pharmaceutical composition containing celecoxib and a dispersion-enhancing amount of an effervescent agent, wherein the dosage form is adapted for swallowing without prior disintegration in water or in the mouth.

Bolt et al. teach a tablet comprising a medicament and an effervescent couple (pg. 7, line 32), where the medicament is selected from non-steroidal anti-inflammatory drugs (pg. 2, lines 40-44). Citric acid and calcium carbonate are specified (pg. 3, lines 3-5). The ratio of acid to base is disclosed to be 4:3 to 1:3 (pg. 3, lines 7-10). A 250 mg. tablet is specified with acid (0.5-20%) and base (0.5-30%) content (pg. 3, lines 17-20). Bolt et al. also disclose that solid dosage forms, which are swallowed, such as tablets and capsules, provide accurate dosage and avoid taste problems (pg. 2, lines 9-10).

However, Bolt et al. fail to disclose the specific non-steroidal anti-inflammatory drug, celecoxib, nor a dosage form adapted for swallowing without prior disintegration in water or in the mouth.

Harrison et al. teach that celecoxib is a non-steroidal anti-inflammatory drug (col. 7, lines 40-42).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use celecoxib as the non-steroidal anti-inflammatory drug in the composition that is taught by Bolt et al. for swallowing without prior disintegration in water or in the mouth.

A person of ordinary skill in the art would have been motivated to include celecoxib because: (1) Bolt et al. teach oral administration of a composition comprising a non-steroidal anti-inflammatory drug; (2) Bolt et al. teach that solid dosage forms, which are swallowed, such as tablets and capsules, provide accurate dosage and avoid taste problems; and (3) Harrison et al. teach that celecoxib is a non-steroidal anti-inflammatory drug. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in producing an effective pharmaceutical composition comprising celecoxib that provides accurate dosage and avoids taste problems.

### ***Response to Arguments***

Applicant argues that Bolt et al. teach away from dosage forms adapted for swallowing without prior disintegration in water or in the mouth because Bolt et al. disclose chewable tablets and taste masking agents.

This is not persuasive because the limitation "chewable" is given little patentable weight since it does not materially change the physical composition disclosed by Bolt et al. Furthermore, since taste problems are associated with chewable tablets, it is obvious to one of ordinary skill in the art to have swallowed the tablet. Examiner views that the chewable tablets disclosed by Bolt et al. can be either swallowed or chewed

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before swallowing, which does not necessarily involve disintegration in the mouth.

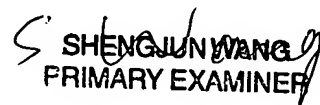
Finally, the claimed composition uses open language in the form of "comprising," which opens for the inclusion of taste masking agents in the composition disclosed by Bolt et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SHENGJUN WANG  
PRIMARY EXAMINER

YSC